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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,578	11/13/2003	Sanjay Awasthi	124263-1006	8252

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,578	AWASTHI ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/28/2006 has been entered.

Claims 1-8 and 47 are currently pending and under consideration.

Objections and Rejections Necessitated by Amendment.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 recites "[T]he method of claim 1 further comprising adding the proteoliposome to the one or more toxic compounds." However, Claim 1 already recites further adding the proteoliposome to one or more compounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Claim 47 has been amended to recite the limitation "wherein the proteoliposome is further

added to a toxic compound in a tissue to deliver the effective portion of RalBP1 for transport of the toxic compounds...." As such, the claims imply that the proteoliposome is directly added to a toxic compound in a tissue. The specification, as originally filed, teaches that the toxic compounds may be present in an organism, mammalian cell, transfected cell, bioreactor, soil, water, spill, process waste stream, manufacturing waste, chemical waster, laboratory waster, hospital waste, and combination thereof, to which the proteoliposome is then added (paragraph 0011). However, the specification and claims as originally filed does not appear to lend support for the limitation of adding the proteoliposome to a toxic compound in a tissue to deliver the effective portion of RalBP1 for transport of the one or more toxic compounds. Applicant is invited to point to clear support or specific examples of the claimed limitation in the specification as-filed or remove such amendatory language in response to this office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Awasthi et al. (Biochemistry 2001; 40: 4159-4168, IDS) as evidenced by Awasthi et al. (Biochemistry 2000; 39: 9327-9334) and Awasthi et al. (Toxicol. Applied Pharm. 1999; 155: 215-226).

Awasthi et al. teach a method of preparing a proteoliposome comprising the step of contacting a liposome with the C- and N-terminal fragments of RalBP1 to create a proteoliposome for the transport of toxic compounds (page 4161, 1st column, Functional Reconstitution in Proteoliposomes). With regards to the C- and N-terminal fragments of RalBP1, the reference teaches that each of the C- and N-terminal fragments of RalBP1includes an ATP binding region for ATP-dependent transport (abstract). With regards to the liposome, the reference teaches (page 4161, line 7) that the liposome is asolectin, e.g. soybean phospholipids. Awasthi et al. further teach (page 4161, 2nd column, Transport Studies) that the method comprises adding the proteoliposome to one or more toxic compounds such as Doxorubicin or Colchicine. For example, the reference teaches (page 4161, 2nd column, Transport Studies and page 4166, Figure 7) that transport studies

were performed using according to the method of Awasthi et al. (2000) comprising adding the proteoliposome in a transport buffer to a specific concentration of either Doxorubicin or Colchicine. Thus, while Awasthi et al. do not specifically teach that the toxic compound was present in a mammalian cell, the claimed limitation does not appear to result in a manipulative difference in the prior arts method because Awasthi et al. (2000) teach that the transport studies were carried out in crude membrane vesicles using K562 cells (page 9329, 1st column, last paragraph). Moreover, while Awasthi et al. do not explicitly teach that the transport of the toxic compounds by the proteoliposome occurs without the assistance of a co-transport molecule, the claimed functional limitation would be an inherent property of the proteoliposome since the specification teaches (page 13, paragraph 0042) that RLIP76 transport does not require GSH co-transport. Thus, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). Furthermore, although Awasthi et al. do not specifically teach that the addition of the proteoliposome protects against further accumulation of the toxic compound and/or prevents the accumulation of toxic compounds, the functional limitation would be an inherent property of the referenced method because as evidenced by Awasthi et al. (1999), a transporter such as DNP-SG ATPase (RLIP76) can act as a mechanism for reducing colchicine accumulation in cells (page 223, 2nd column, 2nd paragraph). Thus, the claimed proteoliposome appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Hence, even though the claims are drawn to a mechanism by which the addition of the proteoliposome to a toxic compound protects and or prevents the accumulation of toxic compounds, the claimed method does not appear to distinguish over the prior art teaching of the same or nearly the same method. The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of

latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Rejections Withdrawn:

The new matter rejection of claims 1-8 and 47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of Applicants Amendment.

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

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